Claim 5, line 2, delete "PFU", and insert therefor -- pfu/kg/day --.

Claim 6, line 2, delete "PFU", and insert therefor -- pfu/kg/day --.

Claim 8, line 5, after "infection", insert -- and lysing a susceptible strain of Entercoccus faecium comprising said colonization with said phage. --

Claim 10, line 2, delete "PFU", and insert therefor -- pfu/kg/day --.

Claim 11, line 2, delete "PFU", and insert therefor -- pfu/kg/day --.

REMARKS

The Written Opinion dated May 29, 2001, has been received and carefully noted. The above amendments and the following remarks are submitted as a full and complete response thereto.

Claims 1-13 are pending. By this response, claims 1, 2, 5, 6, 8, 10 and 11, are amended. No new matter is presented.

Claims 1-13 are free of the prior art.

I. Response to rejection of claims 1-13 for lack of enablement

Under section of VIII of the action, the claims are held to be nonenabled for the following reasons. According to the Examiner, the breadth of the claim scope exceeds the ability of one skilled in the art to practice the invention based on the description in the specification. Claims 1-13 are not enabled for encompassing in vivo effectiveness of the phage strains on VREF hosts, since Merril (USPN 5,688,501) teaches only high does, in vivo administration of phages (106 to 1012 pfu/kg/day) as being effective, Brandt discloses that only antibiotics are effective at eliminating a vancomycin resistant

strain of Enterococcus faecium, and Smith discloses that among several phages tested in different E. coli strains, only one phage strain was effective at eliminating a single strain of E. coli.

Applicant respectfully traverses the enablement rejection and submits the following comments with respect to each of the references cited in the Written Opinion.

With respect to Merril, Applicant is claiming a method of treatment intended for use in humans. At least in the U.S., no court of law has ever held that in vivo human trials were necessary for proving enablement. Thus, under U.S. patent law, method of treatment claims are enabled when supported by in vitro assays and/or in vivo models recognized as corresponding to a human disease or condition. Accordingly, the method of treatment claims (Claims 5, 6, 10 and 11 are drawn to the administered dose (pfu)) find support in Examples 1 and 2 of the original specification demonstrating in vivo efficacy of the phage in a mouse model, and therefore, the claims are enabled. To more particularly set forth the administered dose of phage, claims 5, 6, 10 and 11 have been amended to more correctly recite the phrase "pfu/kg/day" which finds support on page 7 at line 18 of the specification.

As for the Brandt reference, it is stated in the Written Opinion that Brandt discloses that only antibiotics are effective in the elimination of a vancomycin resistant strain of Enterococcus faecium. The Examiner does not cite supporting disclosure for this position because the reference is specifically silent with respect to this position. Brandt does not appear to teach a method of treatment even within the gamut of what Applicant is claiming, and Applicant fails to comprehend the relevancy of the reference in the Examiner's rejection of the claims for lack of enablement.

Additionally, Applicant submits that since the publication of Brandt, the pharmaceutical industry has continued to develop other strategies shown to be effective in eliminating bacterial infections such as for Enterococcus faecium, and such strategies include anti-sense constructs, anti-bacterial peptides and phage encoded enzymes.

As for the Smith reference, Applicant does not agree with the Examiner's interpretation of the abstract nor the resulting conclusion as applied to the instant claims.

Smith specifically teaches that phage pools containing phages specific for different bacterial host strains are effective in eliminating mixtures of those bacterial strains when administered in vivo. What the Examiner mistakes as a single phage being infective for a single strain of E. coli is actually a spontaneously occurring phage that is not present in the starting phage pool. This suggests that not only is the starting population of phage effective in eliminating mixtures of bacterial strains, but that variant forms of phages can appear, and which are just as effective against a given bacterial host strain. In other words, Smith has identified two different phage which are directed against a single strain of bacteria. The Smith reference teaches that not only are phage mutable, but that multiple phage are obtainable for a single strain of bacteria.

More particularly with respect to the present invention, Applicant has identified phage which are effective in eliminating multiple, susceptible bacterial host strains, and claims 1, 2 and 8 have been amended to recite that a bacterial strain is one that is "susceptible" to the phage.

CONCLUSION

Applicant submits that in view of the foregoing arguments and the amendment of the claims, that the claims are fully enabled.

Please charge any fee deficiency or credit any overpayment to Deposit Account No. 01-2300.

Respectfully submitted,

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